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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,660	08/27/2002	Janet Mary Hock	X-13288	9334

25885 7590 12/14/2004

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EXAMINER	
HARLE, JENNIFER I	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,660	HOCK ET AL.	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-62* is/are pending in the application.

4a) Of the above claim(s) *47-58 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *59-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/01/03;*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 47-62 are pending and subject to a Restriction requirement. Applicant elected Group IX, claim 59-61, claims 47-58 and 62 are withdrawn from consideration.

Election/Restrictions

Applicant's election of Group IX, claims 59-61, in the reply filed on October 29, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 47-58 and 62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 29, 2004.

Claims

Applicant submitted a Preliminary Amendment, filed August 27, 2002, canceling claims 1-46 and adding new claims 1-16. Under Rule 1.126, the claims have been renumber as 47-62. Applicant is requested to provide a full copy of the pending claims, whether an Amendment is filed with the next action or not.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 recites the limitation "without concurrent administration of an antiresportive agent other than vitamin D or calcium." It is unclear whether vitamin D or calcium must be administered concurrently with administration of hPTH (1-34) or whether just hPTH (1-34) can be administered alone.

Claim 59 recites the limitation "in a daily dose of at least about 15 micrograms to about 40 micrograms for at least about 12 months up to about 3 years." It is unclear whether this dosage refers back to the hPTH (1-34) or the vitamin D or calcium limitation of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 59 is rejected under 35 U.S.C. 102(b) as being anticipated by Slovik, et al. Restoration of Spinal Bone in Osteoporotic Men by Treatment with Human Parathyroid Hormone (1-34) and 1,25-Dihydroyvitamin D, Journal of Bone and Mineral Research, Vol. 1, No. 4, 1986, pp. 377-381 (submitted by Applicants – but no IDS).

Slovik discloses treating men with idiopathic osteoporsis for one year with a daily subcutaneous self-injection of 400-500 units of hPTH (1-34)[1] plus daily ingestion of 15-30 millimoles of calcium and 0.25 micrograms of 1,25dihydroyvidamin D[2] (Vitamin D/its active

[1] 400 units of hPTH (1-34) is equivalent to 25 micrograms. See Randomised Controlled Study of Effect of Parathyroid Hormone of Vertebral-bone Mass and Fracture Incidence Among Postmenopausal Women on Oestrogen with Osteoporosis, Lancet, Aug. 1997, pp. 550-555 (Abstract only).

[2] 1,25-dihydroxyvitamin D is known as vitamin D or its active metabolite. See, e.g., Vitamin D, Truestar Health Encyclopedia, 2002, www.truestarhealth.com, pp. 1-4; ARS Project: Diet-Gene interaction and Micronutrient Status,

metabolite), which results in significant increases in trabecular bone density in the spine and improved intestinal calcium and phosphorus absorption and total body retention of dietary calcium and phosphorus in middle-aged men, indicating restoration of spinal bone in osteoporotic men and strongly supported the view that the therapeutic approach used increased the patients' skeletal mass, i.e. reducing the risk of both vertebral and non-vertebral bone fracture.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slovik, et al. Restoration of Spinal Bone in Osteoporotic Men by Treatment with Human Parathyroid Hormone (1-34) and 1,25-Dihydroyvitamin D, Journal of Bone and Mineral Research, Vol. 1, No. 4, 1986, pp. 377-381 (submitted by Applicants) in view of Orwoll, et al., Oseoporosis in Men, Endocrine Review, 1995, Vol. 16, No. 1, pp. 87-116 and Jackson, et al., Osteoporosis in Men: diagnosis, pathophysiology, and Prevention, Medicine, 1990, Vol. 69, No. 3, pp. 137-152.

As per claim 59, Slovik discloses as set forth above. Assuming arguendo, Slovik does not disclose reducing the risk of non-vertebral bone fracture, Slovik discloses that hPTH(1034) together with 1,25-dihydroxyvitamin D increases trabecular bone mass in the spine of men and bone mass in general.

2004 Annual Report, pp. 1-4, especially pg. 4; Vitamin D, PCCC Natural Markets, 2004www.pcnaturalmarkets.com/healt/Supp/Vitamin_D.htm, pp. 1-6.

Orwoll discloses that men suffer from non-vertebral and vertebral fractures that result from decline in vertebral trabecular number and thickness, lower trabecular plate density, generalized loss of trabeculae, changes in trabecular structure and loss of trabeculation. See, pg. 91.

Additionally, Jackson discloses that loss of trabecular bone volume is a sign of osteoporosis is a characteristic and pathophysiology leading to fractures. See, pp. 142-143.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention that a method, which increases trabecular bone mass as shown by Slovik would reducing the risk of vertebral and non-vertebral bone fracture in a male human in light of the known mechanism for osteoporosis shown by Orwoll and Jackson.

As per claims 60 and 61, Slovik discloses as set forth above. However, Slovik does not disclose that human subject being treated has osteoporosis arises from a hypogonadal condition, age-related or not.

Orwoll discloses that osteoporsis in men is a heterogeneous condition, encompassing a wide variety of etiologies and clinical presentations, i.e. in practice it is common to uncover several potential explanations for bone loss and fractures in a single patient and one should recognize that each will be rarely encountered in its pure form in clinical situations. Additionally Orwoll discloses that in adult-set hypodonadism, i.e. age-related, vertebral and appendicular bone mass are both reduced, with vertebral bone mass being more pronounced and clear indications of bone remodeling, i.e. trabecular number was reduced in the hypogonadal men, however, remodeling was hetereogenous but animal studies tend to confirm the reduction in trabecular formation findings. See, pg. 98.

Jackson discloses that the concept for distinct osteoporotic syndromes in males has yet to be clearly demonstrated and gonadal function is related to trabecular bone loss, which leads to fractures, i.e. an inclusive mechanism behind idiopathic osteoporisis, as well.

Because age-related hygonadism osteoporosis is a secondary cause of osteoporosis and idiopathic osteoporsis is a primary cause as disclose by Orwoll and Jackson, because they both disclose that osteoporsis is rarely encountered in its pure form, i.e. the causes overlap, and because they both disclose that the mechanism of both idiopathic and age-related hypogonadism have overlapping components, it would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized the method of Slovik to treat a male where the condition is age-related hypogondal osteoporosis.

Claims 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slovik, et al. Restoration of Spinal Bone in Osteoporotic Men by Treatment with Human Parathyroid Hormone (1-34) and 1,25-Dihydroyvitamin D, Journal of Bone and Mineral Research, Vol. 1, No. 4, 1986, pp. 377-381 (submitted by Applicants) in view of Orwoll, et al., Oseoporosis in Men, Endocrine Review, 1995, Vol. 16, No. 1, pp. 87-116 or Jackson, et al., Osteoporosis in Men: diagnosis, pathophysiology, and Prevention, Medicine, 1990, Vol. 69, No. 3, pp. 137-152.

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Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention that a method, which increases trabecular bone mass as shown by Slovik would reducing the risk of vertebral and non-vertebral bone fracture in a male human in light of the known mechanism for osteoporosis shown by Orwoll or Jackson.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Ione Harle
December 7, 2004

MICHAEL MELLER
PRIMARY EXAMINER